

REMARKS/ARGUMENTS

Claims 1-9 were previously pending in this application and stand rejected on various grounds. Claims 1-6 have been cancelled. Claims 10-14 have been added, support for which is found throughout the specification and in the claims as originally filed, and thus do not add new matter. Applicants explicitly reserve the right to pursue any deleted subject matter in one or more continuing applications.

Objections

Claim 1 has been objected to for containing a typographical error. Claim 1 has been cancelled rendering this objection moot.

Claim Rejections Under 35 U.S.C. §112

Claims 1-9 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1-6 have been cancelled, thus the removal of the rejection of Claims 1-6 is requested.

With respect to Claims 7-9, it is the position of the Examiner that “Claim 7 is to a tenecteplase solution composition in a catheter...” and it is unclear how the catheter physically alters the tenecteplase solution. Applicants respectfully point out that the Examiner is misreading the claim. Claim 7 is drawn to an indwelling catheter, not a solution. Thus, it is quite clear to what the invention is directed. Similarly, Claims 8 and 9 and new Claims 10-14 are drawn to a catheter, thus it is quite clear to what they pertain. Therefore, the rejection of Claims 7-9 should be withdrawn.

Claim Rejections Under 35 U.S.C. §103

Claims 1-7 have been rejected under 35 U.S.C. §103 as allegedly obvious over Sandbaek *et al.*, (Blood Coagulation and Fibrinolysis, 1999) as supported by DrugBank (def “Tenecteplase”) in view of Graney *et al.* (Australian Patent AU-B-42810). Sandbaek discloses an investigation of thrombin-related material in arterial thrombi during indwelling catheter-directed thrombolysis with alteplase. Graney discloses tenecteplase that can be included in compositions where the solvent carrier is sterile water. It is the position of the Examiner that

Sandbaek, in view of Graney, teaches the invention as presently claimed. This is not the case and Applicants traverse.

Claims 1-6 have been cancelled, thus the rejection of these claims is moot.

With respect to claim 7, no where does Sandbaek teach or suggest “An indwelling catheter containing... tenecteplase...for a time sufficient to remove fibrin-bound blood clots obstructing the flow of fluids within the catheter”, a required by Claim 7. Sandbaek, in contrast, describes a well-known method of using native-sequence t-PA (alteplase) to dissolve blood clots in arteries. Indeed, the alteplase solution is not allowed to stay in the catheter for *any* extended period of time, since the catheter simply serves as a conduit to deliver the drug to the clot in an artery. Thus, there would have been no reason for one skilled in the art to look to Sandbaek for guidance in teaching the present invention.

The Examiner further cites Graney for teaching a Tenecteplase solution in sterile or distilled water. Graney, however, does not remedy the deficiencies of Sandbaek since no where does Graney teach or suggest “An indwelling catheter containing... tenecteplase...for a time sufficient to remove fibrin-bound blood clots obstructing the flow of fluids within the catheter”. Therefore, the rejection of Claim 7 over Sandbaek in view of Graney should be removed.

As far as the alleged equivalence of alteplase and tenecteplase is concerned, Applicants submit that the two plasminogen activators are not equivalent for the use recited in the claims of the present application. Due to its lower potency, alteplase would be unexpected to effectively remove fibrin bound clots from an indwelling catheter in the concentration ranges and within the time period recited in the claims. Furthermore, from the disclosures of Sandbaek of using alteplase in a dynamic therapeutic setting, one of ordinary skill in the art would not be able to extrapolate the concentration range and the time which are required to ensure that tenecteplase, a significantly different plasminogen activator, effectively remove fibrin-bound blood clots from an indwelling catheter.

It is clear that neither Sandbaek or Graney, either alone or in combination, make obvious the present invention, thus the rejection of Claim 7 should be withdrawn.

Statement of Related Cases

Applicants request the Examiner to consider the following cases which are related to the present application:

U.S. Patent Application Serial No. 11/533,305 filed September 19, 2006

U.S. Patent Application Serial No. 61/013,937 filed December 14, 2007

Other U.S. patents or published applications related to the present application have been cited by US patent or publication number in IDS(s) of record. Applicants request that the Office consider each of these related patents or applications with respect to the present application.

CONCLUSION

The present application is believed to be in *prima facie* condition for allowance, and an action to that effect is respectfully solicited. Should there be any further issues outstanding, the Examiner is invited to contact the undersigned agent at the telephone number shown below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **50-4634** (referencing Attorney's Docket No. **GNE-0239-R1**).

Respectfully submitted,

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